

REMARKS

This is in response to the Official Action mailed January 2, 2003 for the above-captioned application. Applicants request an extension of time sufficient to make this filing timely and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Reconsideration of the application in light of the remarks herein is respectfully requested.

Claims 11-30 are pending in this application. The Examiner has indicated that dependent claims 17, 18, 23, 24 and 28-30 are allowable if amended to independent form, and if the rejection under 35 USC § 112 is overcome.

Claims 11-16, 19-22 and 25-27 stand rejected over US Patent No. WO95/13531. During a telephone conference, the Examiner indicated that greater significance may be being given to this reference because it had the same inventors and contained many of the same drawings and terminology than would have been given had the present application been by a third party. Applicants respectfully submit that the identity of the author of a prior art reference is of no relevance in establishing its significance. Furthermore, as noted below, the drawings and descriptions are not identical, only similar.

Applicants respectfully submit that the present invention is different from the test kit disclosed in WO95/13531 and that the reference therefore cannot be deemed to be anticipatory. In the present invention, as defined in claim 11, the following limitation is found:

a means for initiation of the reading device that engages the assay device in a lock and key relationship.

The Examiner states that this limitation is met by the cited reference at Page 5, lines 5-10. This paragraph, however, reads:

Preferably, said receiving means incorporates interlocking means engagable with corresponding interlocking means on said device to ensure that upon receipt of

said device by said reader said detection zone(s) is located and maintained in a predetermined spacial relationship relative to said reading means.

This paragraph teaches only that the lock and key arrangement ensures proper placement in the reading device. There is no teaching of a lock and key interaction being made with the initiation means. Furthermore, this paragraph cannot be read in isolation from the teaching of the reference as a whole.

The Catt reference, over which the present invention is an improvement, discloses a lock-and-key interaction between an assay device and a reading device. The reading device has an initiation switch, i.e., reference numeral 504. However, as previously noted, in Catt, the reading initiation switch does not participate in the formation of the lock-and-key interaction with the assay device. Note that in Figs. 5 and 6 of Catt, the actuating means is the depressable button 504 "which must be fully depressed to activate the reading mechanism." (Catt, Page 24, line 27-29). The button mechanism does not function, and is not said to function, as a part of the lock-and-key interaction system. In contrast, as reflected in the discussion of Fig. 9 on Pages 11, line 7 et seq., the reading device has protrusions 301, 302 which fit precisely within recesses 703, 704 on the assay device, i.e, in a lock-and-key interaction, "to provide a unique three-dimensional situation in which the switch actuator is actuated by the received assay device."

The Examiner also cites several portions of the disclosure as teaching that "the reading device is initiated when the assay device is positioned correctly within the reading device in the lock and key arrangement." As a first matter, the claims state that the reading device is initiated **only** when the lock and key arrangement is complete. The Examiner statement of the teaching of the reference is broader than the limitation in the claim. Furthermore, the statements cited by the Examiner fall far short of requiring a completed lock-and key engagement as a start of the reading cycle. For example, the passage at Page 26, lines 5-7 relates to structures on the facing surfaces of the reading device and the assay device which insure that the assay device is not inserted upside down. They do not ensure complete insertion in the correct position prior to initiation of the read cycle, because they do not teach a lock and key interaction between **the reading initiation means** and the assay device. The remaining citations all refer to a lock and

key positioning of the assay device relative to the detection system, and thus also fail to teach the present invention. In particular, note that the button or projection 305 referred to at Page 18, lines 1-4 is not said to be a reading initiation means, and indeed is analogous to Fig. Numeral 506 in Fig. 6. Thus, Catt does not anticipate claim 11, nor any of the claims dependent thereon.

The Examiner issued a new ground for rejection of claim 11 for obviousness-type double patenting. Applicants submit that this rejection should not have been made in a final action, and therefore requests that a further Official Action be issued should the rejection not be withdrawn. Nevertheless, Applicants submit that the rejection should be withdrawn on the merits for several reasons.

First of all, the two cited patents claim priority from the same European application and contain the same disclosure as the Catt PCT application which the Examiner cites as a reference. The concept of obviousness-type double patenting is essentially intended to prevent inventors from patenting trivial variations, that would not be patentable to others, because under the law the inventors' own prior patents may not be available as prior art against them. To impose an obviousness-type double patenting rejection where the same subject matter is available as prior art, however, improperly places an inventor on a worse footing than others.

Furthermore, as discussed above, the claimed invention is an improvement over the disclosure of Catt (and thus over the subject matter of the cited US Patents) in which the reading initiation means participates in a lock-and-key interaction with the assay device. The claims of the cited patents do not contain such a limitation, nor is this a trivial variation. The only claims in the '241 patent of those cited that expressly mention an interlocking (or lock and key) arrangement are claims 8 and 9. As is plain from this claim, however, the interlocking occurs to define the spatial positioning of the detection zone relative to the reading means. There is no mention of a lock-and-key interaction between the reading initiation means or "actuating means" and the assay device, and the Examiner has not said why this improvement would be deemed obvious over such a claim. The same is true of claims 5 and 6 on the '619 patent. Thus, contrary to the Examiner's argument, claim 11 is not generic with respect to the claims of the two cited patents, because it specifies a lock-and-key interaction between specific elements (the reading

initiation means and the assay device) which is not required in the claims of the '241 or '619 patent. Thus, Applicants submit that the double patenting rejection should be withdrawn.

Finally, the Examiner has rejected claims 12-14 and 16-30 under 35 USC § 112, second paragraph. Applicants have amended claim 12 in light of this rejection. However, the remainder of the rejection is respectfully traversed.

In claim 11, there is a specific recitation of a detection zone. The phrase "wherein the presence of the analyte ..." which the Examiner characterizes as functional is in fact a description of the physical characteristics of the detection zone, i.e., it is one which is capable of accumulating labeled reagent when analyte is present. Further, this phrase provides antecedent basis for terms used later in the claims. Claim 12 has been amended to make clear the spatial relationship of the porous carrier strip and the detection zone, and that the binding interaction which leads to accumulation of the labeled reagent (i.e., the nature of the detection zone) is one involving specific as opposed to some type of non-specific binding.

With respect to the remaining claims, the Examiner states that these claims are objected to because they should use the term "further comprises." It is pointed out that claims 15, 16, 21, 22, 26 and 27 already use this format, while claims 14, 20 and 25 refer to elements positively recited in previous claims. Thus, the inclusion of these claims in this rejection is not understood. Furthermore, Applicants point out that the standard for compliance with § 112, second paragraph, is not a mechanical standard, but instead depends on whether or not a person skilled in the art could fairly understand the scope of the claims when read in light of the specification. The Examiner has not stated why this standard is not met, but instead has offered statements of mechanical rules and additional verbiage, without stating how the clarity of the claims would be improved. Indeed, it could as easily be argued that the proposed change would introduce ambiguity not presently in the claims.

For example, in claim 12, the porous carrier strip is part of the assay device, not an addition to the assay device as recited. Thus, since the assay device must reasonably be one which is capable of performing an assay, using the phrase "further comprising a porous carrier" might well raise the question of whether two assay systems are required. Similarly, the slot recited in claims 17, 23, 28 and 30 is not a piece (since it is really the absence of physical

structure), but is rather defining the shape of assay device. Thus, saying that the device "further comprises a slot" would be inappropriate.

For the foregoing reasons, Applicants submit that all claims of the present application are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully requested. Should the Examiner have specific concerns or proposals regarding the application, she is encouraged to call the undersigned.

Respectfully submitted,

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MARKED UP COPY OF AMENDED CLAIMS

12. (amended) The test kit of claim 11, wherein said assay device comprises a porous carrier strip disposed within a hollow casing, said porous carrier strip having the detection zone disposed thereon, and wherein the labeled reagent specifically binds to the [porous carrier in the] detection zone.